K073495

510(k) Summary of Safety and Effectiveness

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Application Information:

Date Prepared:	December 11, 2007
Submitter:	TissueLink Medical Inc.
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JAN - 5 2008

Device Information:

Trade Name:	Aquamantys Malleable Bipolar Sealer with Light
Common Name:	Electrosurgery Bipolar Sealer
Classification Name:	Electrosurgical cutting and coagulation device and accessories - 21CFR 878.4400

Predicate Devices:

Claim of Substantial Equivalence of the Aquamantys Malleable Bipolar Sealer with Light is made to:

Name:	Aquamantys 6.0 Bipolar Sealer (Part of the TissueLink Aquamantys Pump Generator System)
510(k) Number	K#052859
Regulation Number	878-4400 Device, Electrosurgical, Cutting & Coagulation & Accessories
Product Code	GEI
Decision Date	October 25, 2005

Device Description

The Aquamantys Malleable Bipolar Sealer is similar to the Aquamantys 6.0 Bipolar Sealer, cleared via K#052859, in that they are comprised of a pencil-grip handle which houses an electrode terminating at the distal tip. The Aquamantys Malleable Bipolar Sealer is constructed of the same medical device grade materials as the Aquamantys 6.0 except for the LED light circuit and over molded shaft. All biocompatibility data is on file at TissueLink Medical, Inc. A summary is included in Section 5 of this submission. The manufacture of both devices is similar, consisting of an electrode tip/shaft assembly extending out of an ergonomically designed clamshell body. Both devices have two parallel (along the axis of symmetry) electrodes stemming from the handle that are approximately 4-6 millimeters apart.

Both devices are electrically insulated, leaving only the tip of each shaft electrically active.

Like the Aquamantys 6.0 Bipolar Sealer, each tip of the Aquamantys Malleable is a smooth stainless steel cylinder with a hemispherical end. Each tip is set at a downward angle between 0° - 45° along the long axis of the device. The Aquamantys 6.0 device has a slot located on each tip oriented lateral to the handle towards the outside of the device, allowing saline to flow from the inner lumen of the hypotube to the electrode. The Aquamantys Malleable device incorporates a hole instead of a slot, similarly oriented lateral to the handle towards the outside of the device. The saline wets the outer surface of the stainless steel electrode tip in a manner identical to the Aquamantys 6.0 Bipolar Sealer. The device is not intended for use without saline.

Ten (10) feet of saline tubing and electrical cord are routed distally from the handle. The distal end of the disposable electrical cord contains a standard three (3) prong paddle plug for connection to the Aquamantys Pump Generator System. The saline tubing is connected to an I.V. pump segment. The I.V. pump segment contains a 6" pump tubing portion for loading into the Aquamantys Pump portion of the Aquamantys Pump Generator System and a Drip Chamber/spike set for connection to the saline delivery source.

The simultaneous application of saline irrigation and radio-frequency energy allows coagulation of bleeding tissue at much lower temperatures than conventional dry radiofrequency coagulation. This prevents the formation of surface eschar. Most conventional electrosurgical devices create a surface eschar that is hard and scab-like.

The Aquamantys Malleable Bipolar Sealer has an optional illumination provided by a LED light positioned between the electrodes at the distal end of the device. It can be switched on or off with a button located on the handpiece and is used to illuminate the surgical site if needed.

The Aquamantys Malleable Bipolar Sealer also incorporates a malleable shaft that can be bent by the user into various positions,while maintaining the functionality as identified in the product specifications.

Figure 1:Aquamantys Malleable Bipolar Sealer with Light – Side View

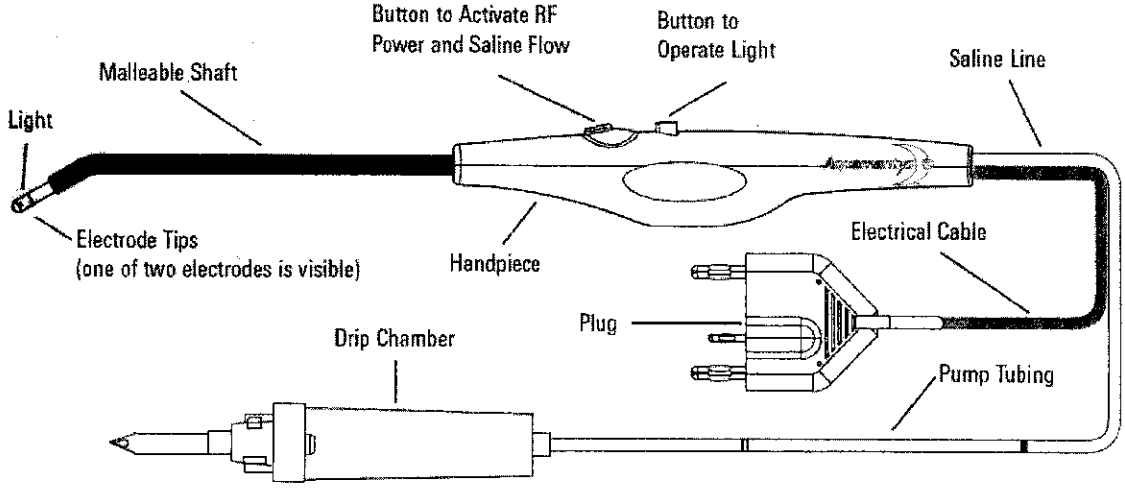
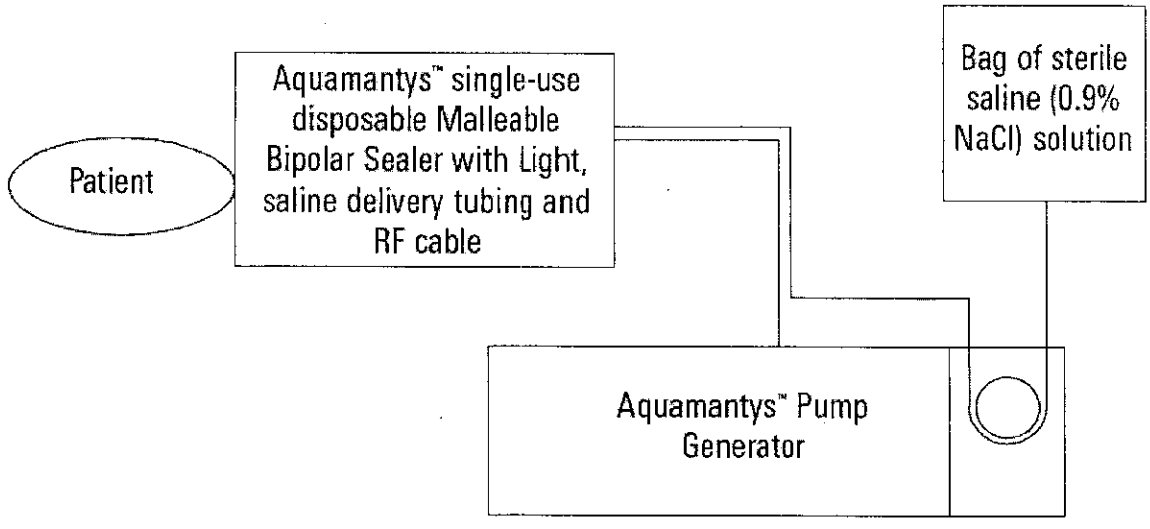


Figure 2: A simple schematic of how the devices connect to other instruments.



Intended Use:

The Aquamantys single-use disposable Malleable Bipolar Sealer with Light is a sterile, bipolar electrosurgical device intended to be used in conjunction with the Aquamantys Pump Generator for delivery of RF energy and saline for hemostatic sealing and coagulation of soft tissue and bone at the operative site. It is intended for, but not limited to orthopaedic, spine, thoracic, and open abdominal surgery. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Contraindications:

The efficacy of the Aquamantys Malleable Bipolar Sealer with Light device for contraceptive tubal coagulation (permanent female sterilization) has not been evaluated and is not known.

Technological Characteristics:

The Aquamantys Malleable Bipolar Sealer with Light electrosurgical device shares the same fundamental technology as predicate device, the Aquamantys 6.0 Bipolar Sealer. The technology is based on simultaneous saline irrigation and RF power delivery. Both devices operate in conjunction with the Aquamantys Pump Generator. No modifications to the Aquamantys Pump Generator software are required for the use of the Aquamantys Malleable Bipolar Sealer with Light.

Nonclinical Performance:
The performance characteristics of the Aquamantys Malleable Bipolar Sealer with Light were tested and compared with performance specifications established by TissueLink Medical, Inc. for the device.

Clinical Performance:
Clinical testing was not performed on these devices.

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Conclusions from Nonclinical Tests:
The performance of this device is substantially equivalent to the predicate device and performs as intended.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

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Dover, New Hampshire 03820

Re: K073495
Trade/Device Name: TissueLink Aquamantys Malleable Bipolar Sealer with Light
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 11, 2007
Received: December 12, 2007

Dear Som Kovvuri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use Statement

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510(k) Number (if known): K073495

Device Name: TissueLink Aquamantys Malleable Bipolar Sealer with Light

Indications for Use:

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Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109)

Optional Format 1-

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073495